PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
CHRISTINE A. LEKUTIS
MEDLEN & CARROLL, LLP
101 HOWARD STREET, SUITE 350
SAN FRANCISCO, CA 94105

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing (*day/month/year*) 07 FEB 2006
Applicant's or agent's file reference DHI-08872	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US04/36689	International filing date (*day/month/year*) 03 November 2004 (03.11.2004)
Applicant DIAGNOSTIC HYBRIDS, INC. AND HEALTH RESEARCH INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report. 4/7/06 RLD

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Mary E. Mosher, Ph.D. Telephone No. 571-272-1600

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference DHI-08872	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US04/36689	International filing date (*day/month/year*) 03 November 2004 (03.11.2004)	(Earliest) Priority Date (*day/month/year*) 03 November 2003 (03.11.2003)
Applicant DIAGNOSTIC HYBRIDS, INC. AND HEALTH RESEARCH INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the Report**
   a. With regard to the language, the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed.
      ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.
2. ☒ **Certain claims were found unsearchable** (See Box No. II)
3. ☒ **Unity of invention is lacking** (See Box No. III)
4. With regard to the title,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,
   a. the figure of the drawings to be published with the abstract is Figure No. _____
      ☐ as suggested by the applicant.
      ☐ as selected by this Authority, because the applicant failed to suggest a figure.
      ☐ as selected by this Authority, because this figure better characterizes the invention.
   b. ☒ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

Inter...

PCT/US04/36689

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 5,61,63,65 and 67
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
These claims are unsearchable because they require particular SEQ IDs, and no Sequence Listing was filed.

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-4 and 18-23

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/36689

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) : C12Q 1/70
US CL : 435/5
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 435/5

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	THIEL et al. Mechanisms and enzymes involved in SARS coronavirus genome expression. Journal of General Virology, 19 June 2003, Vol. 84, ppages 2305-2315, see Figure 1d.	1, 2
X	SNIJDER et al. Unique and Conserved Features of Genome and Proteome of SARS-coronavirus, an Early Split-off From the Coronavirus Group 2 Lineage. Journal of Molecular Biology. 20 August 2003, vol. 331, pages 991-1004, see Figure 3B.	1, 2
X	YOUNT et al. Reverse Genetics with a full-length infections cDNA of severe acute respiratory syndrome coronavirus. PNAS. 20 October 2003. Vol. 100, no. 22, pages 12995-13000, see page 12997-8 and Figure 2B.	1-4
A	KSIAZEK et al. A Novel Coronavirus Associated with Severe Acute Respiratory Syndrome. New England Journal of Medicine. 10 April 2003. Vol. 348, npo. 20, pages 1953-1966, see page 1954.	18-23

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"B" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
04 January 2006 (04.01.2006)

Date of mailing of the international search report
07 FEB 2006

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (571) 273-3201

Authorized officer
Mary E. Mosher, Ph.D.
Telephone No. 571-272-1600

Form PCT/ISA/210 (second sheet) (April 2005)

BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group 1, claim(s) 1-4, 18-23, drawn to detecting replication of SARS virus using PCR to detect subgenomic RNA.

Group 2, claim(s) 6-17, drawn to detecting presence of virus using cultured cells.

Group 3, claim(s) 24-35, drawn to identifying test agent by detecting altered replication.

Group 4, claim(s) 36-39, drawn to antibody.

Group 5, claim(s) 40, 52-54, drawn to composition comprising cells and protease inhibitor.

Group 6, claim(s) 41-47, drawn to method of use of cells with protease inhibitor.

Group 7, claim(s) 48-51, drawn to detecting replication of a coronavirus.

Group 8, claim(s) 55, drawn to method of inhibiting coronavirus 229E.

Group 9, claim(s) 56-60, 62, 64, 66, drawn to kit comprising primers and instructions.

The inventions listed as Groups 1-8 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

PCT article 17 (3)(a) states that "The International Searching Authority shall establish the international search report on those parts of the international application which relate to the invention first mentioned in the claims (main invention) and, provided the required additional fees have been paid within the prescribed time limit, on those parts of the international application which relate to inventions in respect of which the said fees were paid." Pct Rule 13.2 states that "The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

For group 1, the invention first mentioned in the claims, the special technical feature is the detection of SARS subgenomic RNA using PCR, to detect replication of the virus.
Group 2 is drawn to a method of detecting virus, not necessarily detecting replication, and does not require the corresponding special technical feature, as evidenced by claims 8 and 9.
Group 3 is drawn to a screening assay for agents altering replication. It does not require the special technical feature of group I, as evidenced by claims 28 and 29, or provision of a sample for detection of virus or detection of virus as required in group 2.
Group 4 is unrelated to groups 1-3, being drawn to a product-by-process antibody that is indistinguishable from antibodies produced by a different process.
Group 5 does not relate to any of the special technical features of groups 1-4, being drawn to a composition of cells + protease inhibitor.

Group 6 is a method of use of the group 5 composition, which does not require the special technical features of groups 1-4.
Group 7 does not require the special technical feature of group 1, because it does not require detection of SARS replication as evidenced by claim 51.
Group 8 is unrelated to groups 1-7, being drawn to a method of inhibiting a virus different from that of groups 1-4, and having no stated relationship to the products of group 5 or the methods of groups 6-7.
Group 9 is drawn to a kit comprising two coronavirus primers and instructions, but does not require the primers to detect SARS as required in group 1.

Continuation of B. FIELDS SEARCHED Item 3:
EAST USPAT, PGPUB, EPO, JPO, DERWENT; Dialog files 155, 5, 50, 357. Search terms:
SARS, SCOV, HSCOV, ANTIVIRAL, SCREEN?, REPLICAT?, anti adj viral, REPLICAT?, INHIBIT?, VIRUS, SCREEN?, ASSAY, CORONA?, SUBGENOM?, DETECT?, DIAGNOS?, AMPLIF?, LEADER, HEK, HUH, MV1LU, PRIMARY, KIDNEY, 293, 293T, CELL, CELLS, PY=2003, PERSIST?, CPE, CYTOPATHIC, PERMISSIVE, RANGE, INFECT?, LINES, CULTURED, pcr , prhmk

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
CHRISTINE A. LEKUTIS
MEDLEN & CARROLL, LLP
101 HOWARD STREET, SUITE 350
SAN FRANCISCO, CA 94105

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	07 FEB 2006
Applicant's or agent's file reference DHI-08872	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US04/36689	03 November 2004 (03.11.2004)	03 November 2003 (03.11.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): C12Q 1/70 and US Cl.: 435/5

Applicant

DIAGNOSTIC HYBRIDS, INC. AND HEALTH RESEARCH INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☒ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☒ Box No. VII — Certain defects in the international application
- ☒ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	04 January 2006 (04.01.2006)	Mary E. Mosher, Ph.D. Telephone No. 571-272-1600

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/36685

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/36689

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 5,61,63,65 and 67

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international search *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☒ the claims, or said claims Nos. 5,61,63,65 and 67 are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

These claims require specific SEQ IDs, and no Sequence Listing was filed.

☐ no international search report has been established for said claims Nos. _____

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No
PCT/US04/36689

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
   - ☐ paid additional fees
   - ☐ paid additional fees under protest and, where applicable, the protest fee
   - ☐ paid additional fees under protest but the applicable protest fee was not paid
   - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
   - ☐ complied with
   - ☒ not complied with for the following reasons:

   See the lack of unity section of the International Search Report(Form PCT/ISA/210)

4. Consequently, this opinion has been established in respect of the following parts of the international application:
   - ☐ all parts.
   - ☒ the parts relating to claims Nos. 1-4 and 18-23

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No
PCT/US04/36[illegible]

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 18-23	YES
	Claims 1-4	NO
Inventive step (IS)	Claims 18-23	YES
	Claims 1-4	NO
Industrial applicability (IA)	Claims 1-4, 18-23	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-2 lack novelty under PCT Article 33(2) as being anticipated by Thiel et al (Journal of General Virology 84:2305-2315, available 19 June 2003) or Snijder et al (Journal of Molecular Biology 331:991-1004, 20 August 2003). Figure 1d of Thiel shows PCR amplification of a subgenomic RNA comprising a leader sequence, and detection of the amplified product by sequence analysis. Figure 3B of Snijder shows detection of subgenomic RNAs with leader sequences. These meet each and every limitation of the claims.

Claims 1-4 lack novelty under PCT Article 33(2) as being anticipated by Yount et al (PNAS 100:12995-1300, available online October 20, 2003). See page 12998, first paragraph of column 2 for detection of a leader sequence; page 12998, last paragraph of column 1 for detection of genomic RNA; Figure 2B for detection of polypeptide; and the passage spanning pages 12997-12998 for detection of virus.

Claims 18-23 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest cells that support replication of SARS coronavirus in the absence of substantial cytopathic effect, or the use of those cells in a process involving detecting SARS genomic or subgenomic RNA.

Claims 1-4 and 18-23 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No
PCT/US04/36685

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claims 1, 18 are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: Claim 1, line 2 is missing the word "of". Claim 18 recites the abbreviation "pRHMK" without spelling out "primary rhesus monkey kidney" the first time the abbreviation is used in the claims.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04...

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 1-4, 18-23 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim indefinite for the following reason(s): In claim 1, there is no step relating the "detecting" to the purpose set forth in the preamble. This affects dependent claims 2-4. In claim 2, is the intent to require the subgenomic RNA to comprise a portion of a leader sequence, or is the intent to require a PCR primer comprising a portion of a leader sequence? For claims 18-23 as written, the purpose of the assay is not apparent, why detect virus from two samples? What useful information is gained by determining that patient Smith's sample has more subgenomic RNA than patient Doe's sample, or that the Smith and Doe samples make different ratios of subgenomic/genomic RNAs? Are claims 18-23 actually meant to involve comparing the results of different treatments for one (divided) virus sample? Claim 19 is confusing, because it requires detecting an absence of subgenomic RNA while the parent claim requires the opposite, detecting the presence of subgenomic RNA.

Claim 23 is objected to as lacking clarity under PCT Rule 66.2(a)(v) because of the claim not fully supported by the description. The description does not disclose the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art because:.It is apparent that cell lines HEK-293T, Huh-7, and Mv1Lu are required to practice the claimed invention, because these are specifically recited in the claims. The specification does not provide a repeatable method for obtaining these specific cell lines, and they do not appear to be readily available material.